UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, vs. MICHAEL STANLEY KAPLAN, M.D., Defendant.	Case No. 2:13-cr-00377-GMN-CWH **FINDINGS AND RECOMMENDATION**

This matter is before the Court on Defendant Michael Stanley Kaplan, M.D.'s Motion to Dismiss Count One for As Applied Statutory Vagueness (#24), Motion to Dismiss Count One for Failure to State a Federal Offense or Invoke the Jurisdiction of the Court (#25), and Motion to Dismiss Count Two of the Indictment for Failure to State a Federal Offense or Invoke the Jurisdiction of the Court (#27), all filed on April 21, 2014. The Court also considered the Government's Consolidated Response to Motions #24 and #25 (#29) and the Government's Response to Motion #27 (#30), both filed on May 8, 2014. In addition, the Court considered Defendant's Consolidated Reply (#34) and Defendant's Reply (#36), both filed on May 27, 2014. The Court conducted a hearing on June 30, 2014.

BACKGROUND

On October 2, 2013, a federal grand jury returned a two count indictment charging Defendant Michael Stanley Kaplan, M.D., ("Kaplan") with one count of conspiracy to commit adulteration in violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 351(a)(2)(A) and one count of false statement in violation of 18 U.S.C. § 1001. (Indictment #1). Kaplan is a physician licensed to practice medicine in the State of Nevada and specializes in the practice of urology. Kaplan operates a medical practice known as Green Valley Urology ("GVU"), with offices located in Henderson and Las Vegas, Nevada. In the course of his medical practice, Kaplan performs prostate

biopsies. A prostate biopsy is a diagnostic procedure whereby, utilizing a hollow needle, a small sample of tissue is removed from the prostate gland and examined for disease. It is performed in conjunction with a "transrectal ultrasound." (Indictment #1 ¶ 2). A "transducer," or probe, enters the rectal cavity and transmits sound waves; the return echoes are recorded, enabling the physician performing the procedure to make a determination as to where to place the biopsy debris can get trapped." (Indictment #1 ¶¶ 2-4.)

Count One of the Indictment alleges that "[b]eginning on or about December 20, 2010, and continuing to in and around March 2011," Kaplan "re-used, and directed, and authorized and tolerated the medical staff at GVU to re-use" disposable biopsy needle guides multiple times in the performance of a series of prostate biopsy procedures in violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 351(a)(2)(A). (Indictment #1 ¶¶ 13 and 16.) The Indictment defines multi-use needle guides as being "made of a sturdy material, such as stainless steel," that can be "disinfected before each use," and "[t]here is no limit on the amount of times . . . [they] can be re-used." (Indictment #1 ¶ 5). In comparison, the Indictment defines single-use needle guides as similar to "multi-use needle guides, except that they are made of plastic or other disposable material and are intended to be used for one procedure only." (Indictment #1 ¶¶ 6.) The Indictment further alleges that Kaplan's reuse of single-use needle guides resulted in the needle guides being "held under insanitary conditions that rendered them injurious to the health of his patients undergoing procedures requiring a needle guide." (Indictment #1 ¶ 16.) In addition, the Indictment alleges that the needle guides in question were "obtained through interstate commerce, and thereafter used at GVU." (Indictment #1 ¶ 15.)

Count Two of the Indictment alleges that during an interview conducted by federal investigators employed by the Food and Drug Administration ("FDA"), Office of Criminal Investigations on or about March 11, 2011, Kaplan stated that "re-use of single use needle guides at GVU stopped in February 2011." (Indictment #1 ¶ 18.) The Indictment alleges this is a false statement because Kaplan "knew re-use continued at the GVU practice until March 2011" and he did not instruct his medical staff to stop until his medical license was suspended by the Nevada State Board of Medical Examiners on March 14, 2011. As such, the Indictment alleges that Kaplan

knowingly and willfully made a materially false statement in a matter within the jurisdiction of the FDA in violation of 18 U.S.C. § 1001. (Indictment #1 ¶ 18.)

Kaplan seeks to dismiss Count One on two grounds: (1) for as applied vagueness and (2) for failure to state a federal offense or invoke the jurisdiction of the court. Kaplan contends that the single-use needle guides at issue in this action are not "articles" or "held for sale" as required by 18 U.S.C. § 371. Instead, Kaplan claims that the practice of medicine exemption applies, off-label use is permissible, and he did not distribute or charge his patients for the guides. As a result, Kaplan contends that Count One should be dismissed because there is no unlawful object or means of the alleged conspiracy and Section 371 is too vague to clearly include his use of the single-use needle guides. In response, the Government argues that the Indictment is neither vague nor fails to state a crime because Kaplan maintained a commercial relationship with his patients and repeatedly re-used single-use needle guides in his practice. Further, the Government contends that the Indictment plainly alleges the necessary elements to state a violation of 21 U.S.C. §§ 331(k), 333(a)(2), and 351(a)(2)(A) and there is no conflict with Nevada's right to regulate the practice of medicine.

Kaplan also seeks to dismiss Count Two for failure to state a federal offense or invoke the jurisdiction of the court. He contends that this matter is not within the jurisdiction of the FDA because of the arguments set forth as to why Court One should be dismissed, namely, that Kaplan's actions constitute the practice of medicine. Further, Kaplan claims that he did not know that his statement was material or unlawful. In response, the Government claims that Kaplan's statement is within the jurisdiction of the FDA's investigatory power and the allegations of the Indictment are sufficient to state a violation of 18 U.S.C. § 1001.

DISCUSSION

I. Motions to Dismiss Count One (#24 and #25)

Kaplan seeks to dismiss Count One for as applied statutory vagueness and failure to state a federal offense or invoke the jurisdiction of the court. The Government claims that the Count One is neither vague nor does it fail to state a crime. The gravamen of the Court's determination of whether the requested relief is warranted is based on the statutory interpretation of the required elements for the alleged offense.

A. Legal Standard

Federal Rule of Criminal Procedure 12(b) provides that "[a]ny defense, objection, or request that the court can determine without trial of the general issue" may be raised by pretrial motion. A motion to dismiss is generally capable of determination before trial "if it involves questions of law rather than fact." *See United States v. Yip*, 248 F. Supp. 2d 970, 972 (D. Haw. 2003) (citing *United States v. Shortt Accountancy Corp.*, 785 F.2d 1448, 1452 (9th Cir. 1986) (*cert. denied*, 478 U.S. 1007 (1986))). In ruling on a motion to dismiss an indictment for failure to state an offense, the court is "bound by the four corners of the indictment." *United States v. Boren*, 278 F.3d 911, 914 (9th Cir. 2002). The indictment itself should be "(1) read as a whole; (2) read to include facts which are necessarily implied; and (3) construed according to common sense." *United States v. Buckley*, 689 F.2d 893, 897 (9th Cir. 1982) (*cert. denied*, 460 U.S. 1086 (1983)). The court's inquiry must end there; arguments directed at the merits of the claims must be left for trial.

Federal Rule of Criminal Procedure 7(c)(1) provides that the indictment must be a "plain, concise and definite written statement of the essential facts constituting the offense charged." The sufficiency of an indictment is judged by "whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case." *Buckley*, 689 F.2d at 897. Two corollary purposes of an indictment are: (1) to ensure that the defendants are being prosecuted on the basis of the facts presented to the grand jury, and (2) to allow the court to determine the sufficiency of the indictment. *Id*. at 896.

B. Elements of Count One

Kaplan is charged in Count One, pursuant to 18 U.S.C. § 371, with conspiracy to commit the offense of "adulteration" of a medical device (the biopsy needle guide) in violation of 21 U.S.C. §§ 331(k), 351(a)(2)(A), and 333(a)(2).[1] (Indictment #1.) He seeks to dismiss Count One because it fails to allege that he conspired to hold the single-use needle guide devices "for sale" and fails to allege facts showing that he did so. As a result, Kaplan claims that the Indictment fails to state a

[1] These sections are each a part of Chapter 9 of Title 21, known as the "Federal Food, Drug, and Cosmetic Act" ("FDCA" or "the Act").

violation of 21 U.S.C. § 331(k) and fails to invoke the jurisdiction of this court. The Government responds that, because the phrase "held for sale" applies to physicians who use adulterated devices in their medical practice, the Indictment properly states a crime.

The Court finds that the Indictment properly alleges the elements of conspiracy to commit adulteration. "The elements of a conspiracy are (1) an agreement to accomplish an illegal objective, (2) coupled with one or more acts in furtherance of the illegal purpose, and (3) the requisite intent necessary to commit the underlying substantive offense."[2] *United States v. Penagos*, 823 F.2d 346, 348 (9th Cir. 1987). As for element one, the Indictment alleges an agreement was reached between the Kaplan and his medical staff to commit the crime of adulteration, in violation of 21 U.S.C. § 331(k), for the purpose of enriching himself, and describes various acts in furtherance of that agreement, for example, the purchase and use of single use needle guides, as distinguished from multi-use needle guides. (Indictment #1 ¶ 16.)

As for element two, the alleged offense underlying the conspiracy is a violation of 21 U.S.C. 331(k), which provides:

> The following acts and the causing thereof are prohibited . . . [t]he alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

Kaplan states no disagreement with the Government's contention that the Indictment alleges that the needle guide is a "medical device," 21 U.S.C. § 321(h),[3] as defined by the FDCA. (Indictment #1 ¶ 8.) The Indictment sufficiently alleges that needle guides designed for a single use were used in a manner that caused them to become "adulterated," 21 U.S.C. § 351,[4] by re-use and thus, held

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[2] Element three will be addressed below in Section D. Intent to Defraud.

[3] 21 U.S.C. § 321(h) provides that for purposes of this chapter, the "term 'device' . . . means an instrument, apparatus, implement, . . . or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals."

[4] 21 U.S.C. § 351(a)(2)(A) provides that "[a] drug or device shall be deemed to be adulterated . . . if it has been prepared, packed, or held under insanitary conditions whereby it may have been

under insanity conditions rendering them injurious to the health of Kaplan's patients. (Indictment #1 ¶ 16.) However, Kaplan argues that 21 U.S.C. § 331(k) criminalizes only the adulteration of a medical device "held for sale" after shipment in interstate commerce. Moreover, Kaplan claims that the use of an adulterated device by a physician as a diagnostic implement does not equate to the item being "held for sale." The Government responds that the phrase "held for sale" includes a physician's use of needle guides to treat his patients. The Court notes the Indictment does not specifically allege that Kaplan "held for sale" the needle guides; however, it does summarize the language of 21 U.S.C. 331(k) and includes the phrase "held for sale" in the summary. (Indictment #1 ¶ 10.) Therefore, the Court finds the Indictment sufficiently pleads the "held for sale" element, but further analysis is required to determine if Kaplan's use of the single-use needle guides constitutes a "held for sale" action.

C. Held For Sale

It is an essential statutory element of Count One that the adulteration occurred while the item was "held for sale." *United States v. Geborde*, 278 F.3d 926, 932 (9th Cir. 2002). The FDCA provides no definition of the phrase "held for sale." As a result, the Court looks to the "'ordinary or natural' meaning" of the statutory language. *United States v. TRW Rifle 7.62x51mm Caliber*, 447 F.3d 686, 689 (9th Cir. 2006) (courts follow the common practice of consulting dictionary definitions to clarify ordinary meaning). For example, Kaplan suggests the definitions by Black's Law Dictionary's of the term "hold" as "[t]o possess by a lawful title" and the term "sale" as "[t]he transfer of property or title for a price." Black's Law Dictionary (9th ed. 2009).[5] Thus, Kaplan argues that the statutory phrase "held for sale" in 21 U.S.C. § 331(k) should be construed to require that a defendant possess title to goods for the purpose of transferring title to those goods to another party for a price. In contrast, the Government argues that the Merriam-Webster dictionary is a far

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contaminated with filth, or whereby it may have been rendered injurious to health."

[5] Kaplan adds that the Uniform Commercial Code ("UCC"), pertaining to sales of goods, provides that "[a] 'sale' consists in the passing of title from the seller to the buyer for a price." UCC § 2-106.

better barometer of the understanding of a reasonable person of ordinary intelligence and highlights the definition of the term "sale" as "the exchange of goods, services, or property for money." http://www.merriam-webster.com/dictionary/sale, (last visited July 9, 2014). Using this definition, the Government argues that the phrase "held for sale" includes a physician's use of needle guides to treat, that is, to provide a service to his patients.

In *United States v. Geborde*, 278 F.3d 926 (9th Cir. 2002), the Ninth Circuit took a literal view of the phrase "held for sale." Geborde manufactured and gave away a home-made designer drug to several teenagers. He was prosecuted for, among other things, misbranding a drug under 21 U.S.C. 331(k), the same statute under which Kaplan is charged. Geborde's conviction was reversed because of the absence of any evidence to demonstrate that the drug was "held for sale." *Id*. The Ninth Circuit emphasized the applicability of the FDCA to commercial transactions and commercial actors, but found that there was no hint of commercial activity in *Geborde*. In fact, the Ninth Circuit held that, in view of the plain and ordinary meaning of the unambiguous language of that statute, the phrase "held for sale" plainly contemplates a sale. *Id.* at 932.

In determining the meaning of the statute, the Court notes that it should consider not only the particular statutory language, but also the design of the statute as a whole, its object, and policy rationale. *See K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988). The FDCA was "designed primarily to protect consumers from dangerous products . . . from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." *Geborde*, 278 F.3d at 932; *see also United States v. Evers*, 643 F.2d 1043, 1050 (5th Cir. 1981) (holding that the purpose of the FDCA is to protect health and safety of the public and when doctors hold drugs for use in their practice, for distribution to their patients, they hold the drugs for sale within the meaning of section 301(k)). As the Supreme Court explained in *United States v. Sullivan*, 332 U.S. 689, 696-97 (1948), the language of the statute - "while such article is held for sale after shipment in interstate commerce" - was designed . . . to extend the Act's coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer. Therefore, the identity of the ultimate consumer in this case is a significant consideration.

The medical device at issue is a "single use" needle guide. (Indictment #1 ¶ 14). The guide is individually wrapped and marked for single use with a number "2" inside a circle with a line through it, denoting that it should not be used more than once. (Indictment #1 ¶¶ 6-7.) It is made of plastic or other disposable material and is intended to be used for one medical procedure only. *Id.* The Court presumes, utilizing common sense and reasonable inferences as it is required to do, *see Buckley*, 689 F.2d at 899, that the needle guide is intended for a single use because it is manufactured in a way which makes it unsuitable to be reused. There is, therefore, a substantive difference between single use and multiple use needle guides. Because the single use needle guide is expended when it is utilized, it is presumably intended to be disposed of after use. It is not a tool or device which is designed or approved to be used multiple times. Therefore, the Court finds that the patient is the ultimate consumer of the needle guide, not the physician as suggested by Kaplan.

Additionally, Kaplan argues that the patient never comes into title or possession of the needle guide so there is no "sale" to the patient. The Government points out that a sale can also be an exchange of goods, services, or property for money. In this statutory context, both uses of the word "sale" are reasonable. The Court infers, from the allegation that Kaplan operates a medical practice, that patients pay for the medical services provided. The payment undoubtedly reflects the costs of materials used to provide the unique medical service. When a single use needle guide is used for a patient's biopsy, its value and usefulness as a medical device is transferred from Kaplan to the patient in exchange for payment. It has no residual value, at least as a needle guide, because it can only be used once. That Kaplan allegedly resurrected the needle guide for multiple uses by disinfecting it and using it in subsequent procedures does not remove it from being used as part of the commercial transaction to obtain medical services paid for by the patient. Therefore, the Court finds that the Indictment sufficiently alleges that the single use needle guides were "held for sale" within the meaning of 21 U.S.C. § 331(k) to satisfy element two of Count One.

D. Intent to Defraud

In addition, Kaplan argues the Indictment fails to allege an intent to defraud or mislead and,

therefore, Count One fails to allege a felony.[6] He argues that a violation of Section 331(k) is punishable as a misdemeanor unless the accused has sustained a previous conviction under that section or "commits such a violation with the intent to defraud or mislead." 21 U.S.C. § 333(a)(2). Because Kaplan has sustained no previous conviction, the enhanced punishment provisions of Section 333(a)(2) are applicable only if he acted "with the intent to defraud or mislead." The Government disagrees, arguing that the references to Section 333(a)(2) place Kaplan on notice that the Government is invoking the felony provisions. Additionally, it argues that the factual allegations further support that conclusion.

21 U.S.C. § 333(a)(1)-(2) provides:

> Any person who violates a provision of section 301 [21 U.S.C. § 331] shall be imprisoned for not more than one year or fined not more than $ 1,000, or both . . . Notwithstanding the provisions of paragraph (1) [of this section], if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $ 10,000 or both.

(Emphasis added). Consistently, the Indictment alleges that the "FDCA made it unlawful to do any act or cause any act to be done with respect to a device while the device was held for sale after shipment in interstate commerce, if such act resulted in the device being adulterated. 21 U.S.C. § 331(k). Such conduct is a felony when performed with intent to defraud or mislead. 21 U.S.C. § 333(a)(2)." (Indictment #1 ¶ 10.) Further, the Indictment alleges that the conspiracy to aid the crime of adulteration was in violation of Section 333(a)(2). (Indictment #1 ¶ 13.) It also alleges that the object of the conspiracy was to enrich Kaplan in violation of Section 333(a)(2). (Indictment #1 ¶ 14.) Additionally, the Indictment alleges that "Kaplan concealed, and caused to be concealed from his patients, that they were undergoing procedures with re-used needle guides." (Indictment #1 ¶ 17, F.) It further alleges that Kaplan took significant steps – in lying to regulatory investigators, criminal investigators and the general public, including his patients, in a self-serving

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[6] If the object of the conspiracy is a misdemeanor, then the punishment for such conspiracy shall not exceed the maximum punishment provided for such misdemeanor. 18 U.S.C. § 371. A defendant is not entitled to dismissal of the indictment under this argument, only reduced penalties for his conduct.

advertisement - "to conceal his lengthy and unsafe re-use of needle guides." (Indictment #1 ¶ 17, F-G.) Finally, the Indictment alleges that Kaplan re-used needle guides to enrich himself at the expense of his patients' safety. (Indictment #1 ¶¶ 1 and 14.)

As previously indicated, Federal Rule of Criminal Procedure 7 (c)(1) provides that the indictment must be a "plain, concise and definite written statement of the essential facts constituting the offense charged." The sufficiency of an indictment is judged by "whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case." *Buckley*, 689 F.2d at 897. Here, the Indictment adequately alleges that as part of his conspiracy, Kaplan intended to defraud and mislead his patients. In addition to the introductory portion of the Indictment, which indicates that the conduct Kaplan is charged with is a felony if performed with intent to defraud and mislead, the Indictment alleges that he concealed the re-use of needles and lied to investigators and the general public through his advertisements to conceal his conduct. The Indictment also alleges that the object of the illegal acts underlying the conspiracy was to enrich Kaplan at the expense of his patients. Under these circumstances, the Court finds that the Indictment adequately alleges the intent to defraud and mislead, and therefore fairly informs Kaplan of the charge. Whether the Government can prove its case is a matter left to the finders of fact and does not impact the Court's determination of the motions at issue.

E. Void for Vagueness

Relatedly, Kaplan also argues that because 21 U.S.C.§ 331(k) contemplates that the adulterated medical device must be "held for sale," and there is no allegation of any transfer of title to or ownership of the medical device in this case, the Indictment is unconstitutionally vague because a person of ordinary intelligence could not have understood that his conduct was against the law. In response, the Government contends that because the needle guides were used by a physician in the course of his for-profit practice, they were held for sale and therefore, such a setting provides ample notice that his conduct is illegal under the statute.

A statute is unconstitutionally vague "when it does not sufficiently identify the conduct that is prohibited." *United States v. Wunsch*, 84 F.3d 1110, 1119 (9th Cir. 1996); *see also United States*

v. Hogue, 752 F.2d 1503, 1505 (9th Cir. 1985) (a criminal statute is not vague if it provides fair notice of the conduct proscribed.). A statute does not meet this standard when people of ordinary intelligence must "guess at its meaning and differ as to its application." *Id*. (*citing Connally v. General Constr. Co.*, 269 U.S. 385, 391 (1926)); *see also United States v. Hockings*, 129 F.3d 1069, 1072 (9th Cir. 1997) (*citing United States v. Lanier*, 520 U.S. 259 (1997) ("an act cannot be so vague that 'men of common intelligence must necessarily guess at its meaning and differ as to its application.'")). Such laws are void *ab initio* in order to "avoid punishing people for behavior that they could not have known was illegal." *Id*. (*citing Grayned v. City a/Rockford*, 408 U.S. 104, 108-109 (1972).

Section 331(k) criminalizes, in pertinent part, "the doing of an[ ] act with respect to, a . . . [medical] device . . . if such act is done while such article is held for *sale* . . . after shipment in interstate commerce and results in such article being adulterated . . ." (Emphasis added). The Court finds that a person of ordinary intelligence could understand, as discussed above, that when a single use needle guide is consumed or expended during a medical procedure, it is "held for sale" because its usefulness and value are transferred to the patient as part of the price of the medical procedure. *Id.* Unlike Kaplan, the Court is not persuaded that a highly technical definition of held for sale that requires a transfer of title, as stated in the U.C.C., should control over a meaning provided for by common sense. The Court finds that the single use needle guides were held for sale as part of Kaplan's for-profit practice and the ultimate consumer was the patient, which Kaplan was on notice about based on the "single use" marking. (Indictment #1 ¶¶ 6-7.) As a result, the Court concludes that the statute sufficiently identifies the prohibited conduct, it could be understood by a person of ordinary intelligence in the context of the statutory scheme, and is not vague.

F. Usurpation of Nevada's Police Powers

Additionally, Kaplan argues that Count One usurps the police powers of the state of Nevada and its exclusive regulatory authority over the practice of medicine within its borders. Kaplan also argues that his multiple use of single use needle guides is "off-label" use. As such, Kaplan claims that the Indictment fails to allege that the re-use of the needle guides was not in accordance with

procedures that, in his professional judgment, adequately ensured their safety and effective use. The Government argues to the contrary, indicating that under these circumstances there is nothing in the FDCA that hinders Nevada's ability to regulate the practice of medicine. Further, the Government claims that Kaplan's argument as to "off-label" use is irrelevant to the resolution of the usurpation argument and wrong.

It is well settled that the regulation of the practice of medicine is a matter historically committed to the exclusive purview of the States. *Gonzalez v. Oregon*, 546 U.S. 243, 269 (2006). 21 U.S.C. § 396 specifically provides that the FDCA shall not be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.

It is also well settled that the Section 301(k) in itself does not improperly invade the power of the states. *United States v. Sullivan*, 332 U.S. 689, 698 (U.S. 1948). *In United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1319 (D.C. Cir. 2014), a case involving the enforcement of Section 331(k), the defendants claimed that the FDA enforcement of their novel stem cell procedure infringed on states' traditional role in regulating the practice of medicine. The D.C. Circuit recognized the distinction between the regulation of the practice of medicine and the regulation of FDA drugs and devices. They indicated that the focus of the case was upon the mixture being administered to the patient, not the procedures used to administer the mixture. Furthermore, the Court pointed out that to interpret the Statute otherwise:

> would allow states to gut the FDCA's regulation of doctors, and thereby create an enormous gap in the FDCA's coverage, by classifying the distribution of drugs by doctors as the practice of medicine. Given Congress's intent that the FDCA's "coverage be as broad as its literal language indicates," *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969), such a construction is not tenable.

Regenerative Scis., 741 F.3d at 1320. Similarly, in this action, the Government's focus is upon the conspiracy to adulterate the single use needle guide held for sale to the patient, not the procedure used to conduct the biopsy with a needle guide.

Kaplan cites Nevada law that broadly defines the practice of medicine to mean, among other things:

> To diagnose, treat, correct, prevent or prescribe for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality, including, but not limited to, the performance of an autopsy.

Nev. Rev. Stat. Ann. § 630.020. The Court is not persuaded that Count One of the Indictment, charging Kaplan with conspiracy to commit the offense of adulteration of needle guides under Section 331(k), infringes on Nevada's ability to regulate the practice of medicine. Kaplan fails to identify any Nevada law or regulation that is specifically contradicted by the prohibition to allow a physician to reuse a single use needle guide in performing a biopsy. *But cf. Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004) (finding improper the federal criminalizing of physician assisted suicide specifically authorized under Oregon law, thereby altering the "usual constitutional balance between the States and the Federal Government."). Also, the Court finds that a physician's ability to treat patients "by any means or instrumentality" cannot reasonably be interpreted to allow the adulteration of medical devices held for sale to patients. *See Regenerative Scis.*, 741 F.3d at 1320.

Kaplan also claims that using single use needle guides multiple times is authorized as an "off-label" use and not in violation of Section 331(k). The Supreme Court has recognized that "off-label" usage of medical devices - use of a device for some other purpose than that for which it has been approved by the FDA- is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Kaplan's argument, however, points to a defense to the charge rather than a defect in the Indictment. He states that "off-label" use is the ability of the physician to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. Whether the facts support the "off-label" use defense is a matter for the fact finders at trial. *See Yip*, 248 F. Supp. 2d at 972 (a motion to dismiss is generally capable of determination before trial "if it involves questions of law rather than fact."). Therefore, the Court finds that the allegations do not usurp or interfere with Nevada's ability to regulate the medical profession and off-label use is not determinative in the decision to dismiss Count One. In conclusion, the Court carefully considered Kaplan's arguments that Count One is subject to dismissal for as applied statutory vagueness and

failure to state a federal offense or invoke the jurisdiction of the court. The Court is not persuaded that either ground for dismissal applies in this action and will not recommend dismissal of Count One.

II. Motion to Dismiss Count Two (#27)

Kaplan moves to dismiss Count Two because it fails to show that he made a materially false statement "in a matter within the jurisdiction of a federal agency." As a result, Kaplan contends that Count Two fails to state an offense under 18 U.S.C. § 1001 or invoke the jurisdiction of the court. Kaplan refers to his previous argument that Count One purports to improperly usurp the exclusive police power and regulatory authority of the State of Nevada over the practice of medicine within its geographical borders. Based on that argument, Kaplan asserts that Count Two fails to show that he made a materially false statement in a matter "within the jurisdiction of a federal agency" and fails to state an offense. The Government disagrees and argues that the FDA has jurisdiction over the matter investigated and had authority to act upon the information it obtained.

18 U.S.C. § 1001(a)(2) provides:

> [W]hoever, in any matter within the jurisdiction of the executive ... branch of the Government of the United States, knowingly and willfully . . . makes any materially false, fictitious, or fraudulent statement or representation . . . Shall be fined under this Title, imprisoned not more than 5 years . . . or both.

There are five elements necessary to sustain a conviction under Section 1001: a statement, falsity, materiality, specific intent, and agency jurisdiction. *See United States v. Boone*, 951 F.2d 1526, 1544 (9th Cir. 1991). The Indictment alleges that Kaplan knowingly and willingly made a statement, that it was false, material, and made to an agent of the FDA. (Indictment #1 ¶ 18.)

A. Agency Jurisdiction

The Supreme Court has stressed that the term "jurisdiction" in 18 U.S.C. § 1001 should be broadly construed. An agency has jurisdiction within the meaning of the statute when it has authority to act upon the information. *See United States v. Rodgers*, 466 U.S. 475, 479-80 (1984). "The term 'jurisdiction' should not be given a narrow or technical meaning for purposes of § 1001." *Rodgers*, 466 U.S. at 480. A false statement falls within that jurisdiction when it concerns

the "authorized functions of an agency or department," rather than "matters peripheral to the business of that body." *Id*. at 479.

The FDA's authority to investigate is set forth in the Statute. 21 U.S.C. § 372 provides:

> The Secretary is authorized to conduct examinations and investigations for the purposes of this Act [21 U.S.C. §§ 301 et seq.] through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department.

21 U.S.C. § 372(a)(1)(A). The Indictment indicates that the FDA was investigating violations of the FDCA. The FDCA is "designed primarily to protect consumers from dangerous products." *Geborde*, 278 F.3d at 932. Further, the Indictment alleges that the FDA was investigating the re-use of single use needle guides. Needle guides are medical devices subject to the FDCA. *See* 21 U.S.C. § 321(h). The adulteration of medical devices is a matter governed by the FDCA. *See* 21 U.S.C. § 351. Accordingly, the Court has no difficulty concluding that the investigation into the conspiracy to use allegedly adulterated medical devices during medical procedures is within the jurisdiction of the FDA. The FDA has the statutory authority to investigate matters within the purposes of the Act, one of which is to ensure that adulterated products are not sold in interstate commerce.

Kaplan argues that the FDA encroaches upon the authority of the state of Nevada when it attempts to regulate the practice of medicine by investigating medical procedures undertaken by Nevada physicians. For that reason, Kaplan claims that Count Two alleges a false statement over which the FDA has no jurisdiction, and fails to state an offense. To the contrary, the Court has found that under the allegations set forth in the Indictment, enforcement of the FDCA does not prohibit or hinder the regulation of the practice of medicine. *See supra*, Section I. Accordingly, the Court is not persuaded by Kaplan's argument that the FDA lacks agency jurisdiction.

B. Willful and Materially False Statement

Kaplan also argues that Count Two fails to allege that he made a materially false statement to a federal agency with knowledge that the same constituted a criminal offense. Specifically, Kaplan argues that 18 U.S.C. § 1001 requires not only proof that the defendant knew that his statement was false, but also proof that he knew that making the false statement was unlawful. In

addition, Kaplan claims that Count Two fails to state an offense because the allegedly false statement made, that the practice of re-using single use needle guides ended in February rather than on March 14, 2011, is not material. The Government concedes that, in order to find a defendant guilty of willfully making a false statement, a jury must conclude that he acted with knowledge that his conduct was unlawful. However, the Government argues that the Indictment adequately alleges that Kaplan "knowingly and willfully" made a "materially" false statement and further elaboration from the Government as to those elements is not required. As to materiality, the Government insists that the Indictment is sufficiently definite, and materiality is a matter to be resolved by the fact-finders at trial.

As previously stated, the sufficiency of an indictment is judged by "whether the indictment adequately alleges the elements of the offense and fairly informs the defendant of the charge, not whether the Government can prove its case." *Buckley*, 689 F.2d at 897. Here, Count Two follows the wording of 18 U.S.C. § 1001. The Indictment alleges that Kaplan"knowingly and willfully" made a "materially" false statement. (Indictment #1 ¶¶ 18.) Accordingly, the Court finds that the Indictment embodies all the elements of the crime and clearly informs Kaplan of the details forming the basis for the accusation so as to enable him to prepare his defense and to plead the judgment in bar of any further prosecutions for the same offense. *Cooper v. United States*, 282 F.2d 527, 531 (9th Cir. Cal. 1960). The Court notes that a motion to dismiss the indictment cannot be used as a device for a summary trial of the evidence. *United States v. Jensen*, 93 F.3d 667, 669 (9th Cir. 1996). Kaplan appears to be requesting that the Government provide more evidence as to all of the elements rather than merely put him on notice, as required by law. Therefore, the Court will recommend that Kaplan's request to dismiss Count Two be denied because it finds that Count sufficiently states a federal offense and invokes the jurisdiction of the court.

Based on the foregoing and good cause appearing therefore,

RECOMMENDATION

IT IS HEREBY RECOMMENDED that Defendant Michael Stanley Kaplan, M.D.'s Motion to Dismiss Count One for "As Applied" Statutory Vagueness (#24) be **denied**.

IT IS FURTHER RECOMMENDED that Defendant Michael Stanley Kaplan, M.D.'s

Motion to Dismiss for Failure to State an Offense (#25) be **denied**.

IT IS FURTHER RECOMMENDED that Defendant Michael Stanley Kaplan, M.D.'s Motion to Dismiss Count Two for Failure to State an Offense (#27) be **denied**.

NOTICE

Pursuant to Local Rule IB 3-2, any objection to this Finding and Recommendation must be in writing and filed with the Clerk of the Court within fourteen (14) days. The Supreme Court has held that the courts of appeal may determine that an appeal has been waived due to the failure to file objections within the specified time. *Thomas v. Arn*, 474 U.S. 140, 142 (1985). This circuit has also held that (1) failure to file objections within the specified time and (2) failure to properly address and brief the objectionable issues waives the right to appeal the District Court's order and/or appeal factual issues from the order of the District Court. *Martinez v. Ylst,* 951 F.2d 1153, 1157 (9th Cir. 1991); *Britt v. Simi Valley United Sch. Dist.*, 708 F.2d 452, 454 (9th Cir. 1983).

DATED this 9th day of July, 2014.

C.W. Hoffman, Jr.
United States Magistrate Judge